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Mark K. Johnson PO Box 510644 New Berlin, WI 53151-0644				
EXAMINER WOITACH, JOSEPH T				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary**Application No.**

09/932,521

Applicant(s)

HERWEIJER ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 14, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application claims benefit to provisional application 60/225,946 filed August 17, 2000.

Applicants' amendment filed June 14, 2004, has been received and entered. Claim 16 has been canceled. Claims 1-15 and 17-20 have been amended. Claims 1-15, 17-20 are pending and currently under examination.

Inventorship

As it appears that a party required by 37 CFR 1.48(a)(2) to submit a statement of facts may not be willing to submit such statement, applicant should consider either: a) submission of a petition under 37 CFR 1.183 to waive that requirement if the original named inventor(s) has assigned the entire right and interest to an assignee who has given its consent to the requested inventorship correction, MPEP § 201.03, Statement of Lack of Deceptive Intention, or b) refiling the application (where addition is needed under 37 CFR 1.53(b) with a new oath or declaration and any necessary petition under 37 CFR 1.47, or where only deletion is needed, either under 37 CFR 1.53(b) utilizing a copy of a prior oath or declaration under 37 CFR 1.63(d)(1)(iv), or under 37 CFR 1.53(d))(design applications only), thereby eliminating the need for a 37 CFR 1.48 request.

The amendment to the inventorship has been noted, however the statement of facts by an inventor or inventors to be added or deleted does not explicitly state that the inventorship error occurred without deceptive intent on his or her part or cannot be construed to so state.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 17-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, the claims have been amended to recite that practice of the methods results in "prolonging expression" however the literal support for this amendment in the instant specification can not be found (specification-pages 11-19). It is noted that the claims have been amended from 'long term' to 'prolonging', however these terms would not be recognized as analogous in the art and would not be considered to define the same circumstances. The specification sets forth that "this invention relates to nucleic acids enabling long term gene expression" (page 1, lines 8-9) and fails to provide any specific context for interpreting the newly added term "prolonging". Moreover, the specification as a whole teaches the delivery of linear DNA, in particular non-viral vectors, however fails to teach how these in general relates to prolonged expression or how this is assessed.

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To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 1-15, 17-20 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore *specifically point out the support for any amendments* made to the disclosure" (*emphasis added*).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-15, 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Initially, it is noted the amendments to the claims has obviated the basis of each of the specific rejections of record set forth in the previous office action.

Newly amended claims recite and encompass "prolonging" expression, however the metes and bounds of the claims can not be determined without knowing what the term "prolonging" encompasses, or what is being compared to determine if prolonged expression is being achieved by the methods. The claims are indefinite because the term prolonging would be subject to the artisans interpretation and not anything specifically set forth in practicing the claimed invention. As amended, it is unclear how practicing the claimed method steps would not necessarily result in the preamble of the claim and how normal or prolonged expression would differ if a non-viral DNA was delivered and expressed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects

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for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18 stands rejected under 35 U.S.C. 102(e) as being anticipated by Rolland *et al.* (US Patent 6,514,947).

Amendment to the claim 1 to encompass delivery to and expression in a “hepatocyte” has differentiated the claimed invention from that taught by Rolland *et al.* Since amendments to the claims include embodiments not taught in the cited references, therefore obviate the basis of the rejection based on anticipation.

Applicants have correctly pointed out that Rolland *et al.* does not qualify as a 102(b) type reference, however it does qualify as a 102(e) type reference. The rejection is now being made under the correct statute.

Unlike the amendments to claims 1 and dependent claims, claim 18 is still broad, encompassing delivery to any cell type, including those taught by Rolland *et al.* Rolland *et al.* teach a method for the delivery and expression of a nucleic acid vector to an mammal *in vivo* (see summary in abstract and claim 1 for example). More specifically, Rolland *et al.* teach that a nucleic acid vector can be many forms of non-viral nucleic acids including RNA, cDNA and plasmid DNA (column 2, lines 37-40). Furthermore, though it is known in the art that cDNA and RNA are linear nucleic acids, Rolland *et al.* specifically teach that whatever vector used can be provided in a linear form (column 2, lines 58-59). Rolland *et al.* teach that the vector can comprise one or more genes to be expressed (column 2, lines 58-59), and by way of example a reduction to practice using the expression and detection of the luciferase and CAT transgenes is provided (see figures 6 and 8, on sheet 5 of 8). Finally, Rolland *et al.* teach that various routes of

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delivery can be used including within the muscle or interstitial space of a joint (column 2, lines 30-33 and claims 5 and 8). Thus, the teaching of Rolland *et al.* for the delivery of linear nucleic acid sequences and expression of said sequences *in vivo* anticipates the instantly claimed invention.

As noted previously, the unexpected results relied upon by Applicants are not active method steps, rather they are an inherent consequence of practicing the method as claimed and as taught by Rolland *et al.* As acknowledged by Applicants Rolland *et al.* teach the formulation of all known polynucleotides, so with respect to Rolland *et al.* teaching away, Examiner can not find any negative teaching of why the artisan would not use the form of liner DNA. Rolland *et al.* provide for methods for the delivery of a polynucleotide that when expressed produces a protein to provide the basis of a vaccine in a mammal. It is acknowledged that Rolland *et al.* do not specifically compare the expression pattern of various polynucleotides, however they clearly provide the limitations to practice the method as claimed. The expression of any DNA in a cell is a property dependent on many factors including the amount delivered, the to which it is delivered, the promoters used, and the complexity of sequence expressed, however in total is an inherent property of any of the polynucleotides delivered. As noted in the previous office action, where the claimed and prior art process are identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie* obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same; and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433

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(CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). In the instant case, because the teachings of Rolland *et al.* meet the structural limitations for practicing the methods as claimed, one would consider any functional limitation resulting from this practice would inherently result in the functional limitation set forth in step (b). Further, given the general and limited guidance of the specification for the types of polynucleotides contemplated for use in the claimed methods, there is no teaching nor evidence that any particular sequence that is provided in a linear form would not inherently result in the specific expression levels recited and required by the instant claims. Therefore, even though Rolland *et al.* do not specifically teach the functional limitation set forth in the claims that Applicants argue distinguishes the claimed invention from that disclosed, simply delivering any linear polynucleotide sequence would inherently result in this functional limitation.

With respect to the declaration filed under 1.132, there is no information in the declaration to antedate nor differentiate the instantly claimed method from that disclosed by Rolland *et al.*

Claims 1, 5, 7, 18 and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Nabel *et al.* (US Patent 5,733,543 issued March 31, 1998) is withdrawn.

The amendment to the claims has differentiated the claimed invention from that taught by Nabel *et al.*

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 14, 15, 18 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Rolland *et al.* (US Patent 6,514,947) or Nabel *et al.* (US Patent 5,733,543) in view of Budker *et al.* (Gene Therapy, 5:272-276, 1998) is withdrawn.

The amendments to the claims has differentiated the claimed method from that made obvious by Rolland *et al.* in view of Budker *et al.*

The unexpected results for expression in hepatocytes as presented by Chen *et al.* are noted, however the reliance of unexpected results must be presented in the specification and commensurate in scope with that which is being claimed. In the instant case, there is nothing in the specification that would have specifically indicated the results obtained by Chen *et al.*, nor that his results would extend to any and all cells beyond the specific construct he had used in his experiments.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
A01632